

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION, FIELD OPERATIONS BRANCH, COMPLIANCE

4298 Elysian Fields Avenue New Orleans, LA 70122 Telephone (504) 589-7166 Fax (504) 589-4657

December 29, 1997

WARNING LETTER NO. 98-NOL-12

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Larry Romero
District Manager
Baker Hughes Inteq
P.O. Drawer 490
Broussard, LA 70578-0490

Dear Mr. Romero:

FDA inspected your vessel watering point, located at 464 Davis Road, Cameron, Louisiana on December 9, 1997.

The observations made during the inspection are in violation of the Public Health Service Act and the Food Drug and Cosmetic Act as promulgated in Title 21, Code of Federal Regulations (CFR), Parts 1240 and 1250.

During the inspection, the following violations were noted:

- 1. No cap on potable water hydrant number 1;
- 2. no check valve/backflow preventer on potable water hydrant number 2;
- 3. both potable water hydrants were not identified for their intended use.

The list of inspectional observations, identified above, is not intended to be an all-inclusive list of the conditions observed at your facility. It is your responsibility to assure adherence with all requirements of the regulations.

Based on inspectional findings, we are classifying the vessel watering point as <u>PROVISIONAL</u> for interstate carrier use for a period of thirty (30) days. A "Provisional" classification means that the watering point may continue to operate; however, significant corrections of violations must be made by the expiration date. On or about that date, a reinspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made at the time of the next inspection, the facility will be reclassified as NOT-APPROVED for carrier use.

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Please advise this office in fifteen (15) days of the receipt of this letter regarding the measures you have implemented to correct the violations. Your response should include a discussion of any delays you foresee in achieving correction, and a deadline by which correction can be expected. Please direct your response to Mr. Richard D. Debo, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, LA 70122-3896, telephone number (504) 589-7166, fax number (504) 589-4657.

Sincerely,

James E. Gamet

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District Director

New Orleans District

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Enclosure: FDA-483

cc: Mr. Robert W. Landreneaux

Marine Base Manager
Baker Hughes Inteq
P.O. Box N (464 Davis Road)

Cameron, LA 70631